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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003905954 for a patent by PATIENTRACK PTY LTD as filed on 29 October 2003.



WITNESS my hand this Tenth day of November 2004

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PATIENTRACK PTY LTD

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PROVISIONAL SPECIFICATION

for the invention entitled:

"System and method for improving the provision of health care"

The invention is described in the following statement:

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SYSTEM AND METHOD FOR IMPROVING THE PROVISION OF HEALTH CARE

FIELD OF THE INVENTION

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The present invention relates to systems and methods for improving the provision of health care. In particular, the invention relates to provisions of health care in a hospital environment, facilitated by a centralised computer administration system.

10 BACKGROUND OF THE INVENTION

Hospital ward environments have traditionally been operated on the basis of set procedures to be followed by health care personnel in relation to the provision of patient care. These procedures are often purely manual and rely greatly on the exercise of the skill and judgement of the attending health care personnel to ensure that the patient's needs are adequately attended to. Because of the significant reliance on the human faculties of the health care personnel, mistakes and oversights are inevitable in a busy hospital environment.

Statistics indicate that between 4% and 18% of hospital admissions have been associated with an adverse event caused by inadequate medical management. A recent study of the quality of Australian health care found that 16.6% of hospital admissions were associated with an adverse event, and that 18.5% of these adverse events resulted in permanent disability or death. In Australia, this translates to 14-18,000 deaths per annum and in the order of 50,000 injuries as a result of adverse events. The projected cost of these adverse events to the Australian healthcare system is in the order of AU\$2 billion. Similar studies in the United States, United Kingdom and New Zealand have confirmed the magnitude of this problem. Significantly, a further analysis of these events found that up to 70% of them were potentially preventable.

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Many adverse events are caused by human error and failure of administrative processes.

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These may include:

- (a) failure to synthesise, decide and/or act on available information;
- (b) failure to request or arrange an investigation, procedure or consultation;
- (c) lack of care or attention;
- 5 (d) failure to attend;
 - (e) delay;
 - (f) misapplication of, or failure to apply, a rule, or use of a bad or inadequate rule.

It would be beneficial to provide a medical software application for use in a general hospital ward environment that is designed to prevent a significant proportion of these adverse events.

SUMMARY OF THE INVENTION

15 The present invention provides a system for facilitating the provision of health care to at least one patient, including:

computerised mean's for logging patient data relating to said at least one patient;

an administration system in communication with said computerised means and configured to determine a risk status of said at least one patient based on the related patient data, said administration system being further configured to: transmit a first direction to first predetermined health care personnel to attend the at least one patient, depending on the determined risk status; determine whether the first predetermined health care personnel has confirmed attendance on the at least one patient within a first predetermined time period; and transmit a second direction to second predetermined health care personnel to attend the at least one patient within a second predetermined time period if attendance by the first predetermined health care personnel was not confirmed within the first predetermined time period.

Preferably, the second predetermined time period is equal to or less than the first predetermined time period. Preferably, the first and second directions are effected by automatic transmission of a message to a portable electronic device associated with the

respective first or second predetermined health care personnel. Preferably, the first and second directions are transmitted as wireless communications. Preferably, the patient data includes data relating to a plurality of health parameters. Preferably, the first direction is only transmitted when the risk status is equal to or above a threshold level.

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Preferably, the first and second directions include information concerning the determined risk status of the at least one patient. Preferably, the first and second directions include a request to confirm that the relevant health care personnel intends to comply with the direction.

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Preferably, the administration system increases the risk status of the at least one patient if it determines that the first predetermined health care personnel has not confirmed attendance on the at least one patient within the first predetermined time period.

Preferably, the administration system is further configured to determine whether the second predetermined health care personnel has confirmed attendance on the at least one patient within the second predetermined time period and to transmit a third direction to third predetermined health care personnel to attend the at least one patient within a third predetermined time period if attendance by the second predetermined health care personnel was not confirmed within the second predetermined time period. Preferably, the third predetermined time period is equal to or less than the second predetermined time period.

Thus, if the patient is still not attended to by the first or second health care personnel within a particular period of time, third health care personnel can be contacted to attend the patient. In effect, this allows the escalation of the risk status of the patient so that more senior medical staff can be contacted and shorter time frames may be provided for attending to the patient. Thus, the administration system will continue to monitor the patient's status and whether she has been attended to by the relevant health care personnel and will continue to transmit directions to health care personnel as appropriate. Thus, it is possible that four or five directions may issue and the risk status may be increased with the issue of each direction to ensure that the patient receives the necessary care.

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Preferably, the computerised means include a plurality of computerised devices networked with, but located remotely from, the administration system. Preferably, each computerised communication device is located nearby the at least one patient. Preferably, the computerised device is a wireless handheld device. Alternatively, the computerised device may be a personal computer with appropriate input means for logging the patient data.

Preferably, the administration system includes a centralised server having a risk assessment module for determining the risk status and a communications module for transmitting directions to health care personnel.

Preferably, directions to predetermined health care personnel are transmitted to the health care personnel by at least two contact media. For example, the direction may be transmitted to a doctor's pager and, shortly thereafter, or simultaneously, be transmitted to the doctor's mobile phone. The direction may also be in the form of a recorded voice message directed to the doctor's office telephone number. If the patient is at the highest risk status, the communication module may transmit the direction to all contact devices associated with the health care personnel at the same time.

The invention further provides a method for facilitating the provision of health care to at least one patient, including the steps of:

receiving patient data relating to said at least one patient;

determining a risk status of said at least one patient based on said patient data;

transmitting a first direction to first predetermined health care personnel to
attend the at least one patient, the first direction including the risk status of the at least one
patient;

determining whether the predetermined health care personnel confirms attendance on the at least one patient within a first predetermined time period; and

transmitting a second direction to second predetermined health care personnel to attend the at least one patient if attendance by the first predetermined health care personnel was not confirmed within the first predetermined time period.

Preferably, the second direction includes an increased risk status of the at least one patient.

Preferably, the second direction includes a second predetermined time period for attending the at least one patient. Preferably, the first predetermined time period is associated with the determined risk status and the second predetermined time is associated with the increased risk status.

Preferably, the second predetermined time period is equal to or less than the first predetermined time period.

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Preferably, the method further includes the steps of:

determining whether the predetermined health care personnel confirms attendance on the at least one patient within the second predetermined period; and

transmitting a third direction to third predetermined health care personnel to attend the at least one patient if attendance by the second predetermine health care personnel was not confirmed within the second predetermined time period. Preferably, the third direction includes a further increased risk status of the at least one patient.

Preferably, the third direction includes a third predetermined time period for attending to the at least one patient, the third predetermined time period being equal to or less than the second predetermined time period. Preferably, the third predetermined time period is less than the first predetermined time period.

The present invention further provides a patient care system including:

at least one electronic device for recording patient data relating to the health of at least one patient;

a central server in communication with the at least one electronic device and configured to repeatedly contact one or more health care personnel to request attendance on the at least one patient if the patient data indicates that the health of the at least one patient is above a predetermined risk level and the patient is unattended by the one or more health care personnel.

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The present invention further provides a patient care system, comprising:

means for determining a risk level of a patient; and

means for repeatedly contacting one or more medical or health care personnel to attend the patient if the risk level is above a predetermined level and the patient is unattended by said personnel.

The present invention further provides a patient care method, comprising the steps of: determining a risk level of a patient; and

repeatedly contacting one or more medical or health care personnel to attend the patient if the risk level is above a predetermined level and the patient is unattended by said personnel.

Embodiments of the invention are concerned with the health of the individual patient by providing the bedside nurse and front line doctors with a real time solution for any deterioration in a patient's clinical status. The system communicates with caregivers by graded alerts that are configurable to any healthcare setting. The graded alerts assist in task prioritisation for bedside nursing and medical staff based on the severity of the documented bedside observations. Advantageously, information capture by the system allows the audit and analysis of individual patient and provider performance by any healthcare organisation.

BRIEF DESCRIPTION OF THE DRAWINGS

25 Figure 1 is a block diagram of a system according to one embodiment of the invention;

Figure 2 is a flow chart illustrating a method according to one embodiment of the invention;

30 Figure 3 is a block diagram illustrating operation of risk assessment functions of the system;

Figure 4 is a flow chart illustrating risk assessment of a neurological system of a patient;

Figure 5 is a flow chart illustrating risk assessment of a respiratory system of a patient;

Figure 6 is a flow chart illustrating risk assessment of a cardiovascular system of a patient;

Figure 7 is a flow chart illustrating risk assessment of a urinary system of a patient;

10 Figure 8 is a flow chart illustrating risk assessment of patient temperature;

Figure 9 is a flow chart illustrating operation of a communications module of the system; and

15 Figure 10 is a block diagram of an application service provider (ASP) model of the system according to one embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 Embodiments of the invention relate to a hospital communications and clinical guidance system that collects, analyses and alerts the appropriate medical staff of projected at-risk patients in a general hospital ward environment.

Referring now to Figure 1, a system 100 is shown for facilitating the provision of health care to at least one patient, and possibly in the order of a 1000 patients, in a hospital ward environment. The system 100 includes an administration system 105 in communication with a number of remote data inputs 135 for receiving patient data corresponding to patients receiving care in the hospital beds. Such data capture devices 135 rely on nursing or other clinical staff to examine each patient on a regular basis and input observations concerning the patient's physical state into the data capture device 135 for communication to the administration system 105. The administration system 105 processes the patient

data received in this way and communicates with one or more health care personnel 145 as appropriate, depending on the severity of the condition experienced by the patient.

The administration system 105 may be in the form of a central server located on the hospital premises or remotely therefrom but in communication therewith. Patient data collected from the data capture devices 135 are stored in data storage 140 associated with the administration system 105. Given the large amount of data required to be collected in a normal hospital environment on a daily basis, the data storage 140 necessarily has large storage requirements and includes a suitably large database.

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The administration system 105 includes a data repository 110 for interfacing with data capture devices 135 and data storage 140. This data repository 110 provides patient data to a risk assessment module 115, which processes the information to determinate a risk status level of the patient. The risk status level information is provided to a communications module 120 within the administration system 105, which then transmits a direction or request (also called an alert message) to relevant health care personnel 145 to attend the patient. The communications module 120 interfaces with a human resources module 125 within the administration system 105 to determine which health care personnel should be contacted for a particular patient.

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The administration system 105 also includes an event logging and system analysis module 130 for logging and tracking the performance of the administration system 105. The purpose of the event logging and system analysis module 130 is to enable data mining, report generation and critical analysis of the level of service being provided to the patients.

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The event logging and system analysis module 130 enables hospital management to track clinical performance from both a patient care and business efficiency perspective. It enables management to identify issues that require resolution when things go wrong, and assists in identifying personnel performance which requires improvement.

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The system 100 is specifically designed for a general ward environment where scope for

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adverse events and failure to detect such events is high. The system 100 evaluates basic clinical data of the type inputted currently by nurses into hand-written charts. With the system 100, nurses input patient clinical data at regular intervals directly into the capture device 135 which preferably a personal digital assistant (PDA), PC or electronic tablet, instead of the current hand-written bedside observation chart. The observation data is transmitted from the capture device 135 to the data repository 110, after which it is forwarded to the risk assessment module 115. The risk assessment module 115 continuously evaluates patient data parameters (including blood pressure, heart rate, respiration rate, oxygen saturation, consciousness level, urine output temperature and pain score) against known safety benchmarks for each parameter. The risk assessment module 115 evaluates data-points with values outside of the normal 'safety range' in each of the parameters and assigns a total risk index value. The higher the risk index value, the more likely that a patient may be experiencing, or about to experience, a critical event. The risk index value determines whether intervention activity is required. Each hospital sets its intervention activities according to the index value thresholds that meet its own risk criteria. When a patient's risk index is equal to or higher than an intervention threshold, the communication module 120 communicates a message to the appropriate nursing or physician resource requesting intervention action, such as beside attendance or cardiac arrest management. The higher the level of risk, the more rapid and more senior the response resource required to attend the patient. 20

The communications module 120 that delivers the medical intervention alerts to health care personnel is configurable to enable multiple communications devices (eg mobile phone/SMS, pagers, PDA etc) to be contacted for each doctor or other care providers. The alert message may include the patient's observation data, the patient's risk status and associated required response time and a short message requesting the health care personnel If the health care provider does not respond to an alert, to confirm attendance. communication module 120 identifies the next most appropriate health care personnel and sends a request to that person to undertake the relevant intervention activity. If that person does not respond, or responds but does not attend the bedside within the prescribed time, the communication module 120 contacts the next most appropriate health care personnel

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and so on. The administration system 105 allows the hospital to configure the required response time depending on the risk level of the patient. Hospital administration is alerted by the administration system 105 to situations where there are health care resource problems, (quality and quantity) in emergency circumstances that require administrative intervention.

The human resources availability module 125 maintains current staffing and roster records and supports the communications module 120 by providing up-to-date information on the physician/health care resources that are available to respond to requests for bedside intervention. This prevents requests being made for intervention that are not likely to be met due to non-availability of health care personnel.

The administration system 105 is a governing system within which the modules described above operate. Additionally, the administration system 105 is responsible for allowing the hospital to set the operational parameters, for example such as the kind and frequency of data capture, the basis upon which the risk assessment is performed, the time periods allowed for responding to the alert messages and the methods of communication therefore. Thus, an essential function of the administration system 105 is the set up and configuration of the various modules which operate within it. A further essential function is to act as a user interface with the system 100, such that health care personnel and hospital administrators can check on patient health and ensure that an appropriate level of care is provided to the patients.

Other administration tasks are also implemented through the administration system 105, such as:

- User rights and privileges
- Graphical user interface configuration and content management
- Initial and ongoing systems Configuration
- Systems settings, back up and management
- 30 Data import and extraction
 - Updating, refining and logging risk assessment benchmark changes

Privacy requirements

As a part of hospital admission, a patient record is established for each patient, after which the system 100 relies on the timely and regular input of patient health data. Previously, that data was captured manually by a nurse or medical officer into a manual chart or document. The 100 system uses an electronic capture mechanism 135 (in the form of a PDA, PC, or electronic tablet) whereby nurses input required clinical data into the device at or nearby the patient's bedside. The nurse also sets up the patient profile for administrative information of the type outlined below.

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The data collection model for patient information includes:

- Patient details (name, DOB, treatment address, patient id, ward etc) with appropriate privacy security. This information is required to establish a patient record so that a patient's risk level can be monitored.
- The required patient bedside observation parameters that form the basis of the risk assessment projections, including blood pressure, heart rate, respiratory rate, level of consciousness, temperature, pain score, oxygen saturation, urine output, Do not resuscitate status and other factors such as co-morbidity factors. Further observation parameters may be established if considered to play an important role in indicating the possibility of an adverse health event.

Data is entered by authorised medical staff including nurses, junior doctors, registrars and consultants by entering a common login identification code (eg staff number) and a specific user configured password.

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The system 100 can be configured to request medical staff to collect data over different durations (eg every 15, 30, 60 minutes), depending on the patient's risk level and hospital policy.

30 The system 100 follows a thin client model, with the patient information held on a central server or database 140. The patient observation data and patient record may be displayed

at the bedside with PDA, tablet or PC 135 if requested by authorised personnel. For example, the capture device may be configured to read a bar code on an ID tag of the health care provider to determine the relevant authorisation. Nursing staff can use the administration system 105 to print hard copies of the observation charts and data via the WLAN to a number of network printers thoughout the hospital. The data repository 110 may draw data from existing hospital systems, such as a PAS (patient administration system).

While a patient continues to receive care, the risk assessment module 115 continuously evaluates patient data parameters (for example, including blood pressure, heart rate, respiration rate, oxygen saturation, consciousness level, urine output, temperature and pain score) against certain benchmarks for each parameter. A series of algorithms evaluate data from the following five key health systems:

15 System 1 - Neurological

System 2 - Respiratory, respiration rate and oxygen saturation

System 3 - Cardiovascular, blood pressure and heart rate

System 4 - Urine System

System 5 - Temperature

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The risk assessment module 115 evaluates data-points across all the key systems above to determine values outside of the expected normal range in each of the parameters and calculates a total risk index value. The values outside the normal range are unexpected negative and positive variations against the range that is considered 'normal'. If any one of the key parameters is assessed to be critical or dangerously outside the expected range value, the risk assessment module 115 automatically assigns the highest risk status (status level 5) to the patient and communicates a request for urgent intervention through the communications module 120 to an appropriate physician resource (for example, such as a cardiac arrest team).

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Where none of the key parameters are assessed to be individually dangerously outside the

expected or normal range, risk assessment module proceeds calculate a risk index. This risk index is based on the sum of the absolute values of the negative and positive deviations from the expected range for each of the above health. Generally, the bigger the deviation from the expected range across each parameter, the higher the risk index and the more likely a patient will experience, or is currently experiencing, a critical event. On the basis of the risk index the patient is automatically assigned a risk status by the risk assessment module 115. The risk index is configured by the hospital to equate to a status level which in turn drives a required intervention response which is communicated to the appropriate health care personnel by communication module 120.

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Embodiments of the invention contemplate at least six risk statuses:

Status Level 0 - Patient stable

This status level indicates that the patient data is within an expected range and patient's overall condition is considered to be stable.

Status level 1 – Non Urgent Review (3-8 hrs)

This status level occurs where a patient's observations are outside expected range but no immediate or urgent intervention activity is required. The patient should be attended within about 3 to 8 hours. The implied instability may self-correct as the patient continues his recovery or may be an indicator that there is an issue that requires treatment. An issue requiring treatment would be indicated by a continued non-zero risk status or an increased risk index value.

25 Status Level 2 - Timely Review Required (1-3hrs)

This status level occurs when the patient's observation values are abnormal and the patient requires review within 1-3 hours. The implied instability may self-correct as the patient continues her recovery or may be an indicator that there is an issue that requires addressing. An issue requiring addressing would be indicated by a continued non-zero risk status or an increased risk index value.

Status Level 3 - Urgent Assessment Required (10mins - 60mins)

This status level occurs when the risk index is materially outside the expected range in one or more of the systems or when the status has been escalated from level 2. This indicates an elevated risk of a critical health event and indicates that the patient's health is unstable.

5 The patient should be attended within about 10 to 60 minutes.

Status Level 4 - Immediate Response Required (0-10mins)

This status level occurs when the risk index indicates that one of more of the core parameters are substantially outside the expected range indicating that the patient is at risk of an impending cardiac arrest or other serous health risk. The patient should be attended within 10 minutes.

Status Level 5 - Cardiac Arrest Call (immediate)

This status level may occur when the Patient is suffering a cardiac arrest or other lifethreatening condition and requires immediate intervention by medical personnel, such as the cardiac arrest team.

The risk index value determines the status level that is assigned to a patient. The above intervention activities are mapped against the status levels and the status level determines the intervention activity, if any, that is required.

A greater number of status levels, risk index values and greater variety of intervention activities may be configured into the system 100 to accommodate a perceived need for such. Similarly, the described response times may be configured to accord with the desired service response level of the hospital or ward. However, for present purposes of illustration, only the preferred six status levels are described.

A patient's health risk is assessed on a 0-5 scale as outlined above and the risk index is calculated using the following rules:

1. If any one health system scores the maximum number of points (i.e. 5 points) then

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- the patient has reached the critical threshold and immediate intervention is required.
- 2. Where any more than one system (eg neuro, respiratory, cardiovascular) has unusual observations, 1 point only is added for the involvement of an additional system or systems that is above the status level 0 threshold.
- Where an intervention request has been sent to an assigned health care resource and that resource does not respond within the required time limit, the risk index is increased by 1 point over and above the index value assigned to the patient on the basis of observation data.
- 4. A not for resuscitation NFR order modifies that number of status levels from 6 (0-10 5) to 5 (0-4).
 - 5. No more than 5 risk index points can be assigned to a patient. A maximum of 4 points is assigned if the patient is not actually undergoing a cardiac arrest or similar level of danger to the patient's health (ie. loss of consciousness).
- 15 Each hospital sets the intervention activities according to a status level (0-5) that is assigned on the basis of the risk index value and that meet its own risk criteria. When a patient's risk index is higher than an intervention range threshold (eg. level 0), the system 100 communicates a message to the appropriate health care provider resource 145 via the communications module 120.

The risk assessment module 115 will continuously assess risk based on observation data or other pertinent data, calculate a risk index value and assign a status level until either a patient is discharged or dies.

The purpose of the NFR option is to ensure that patient's wishes are met in respect of treatment and it allows the terminally ill to receive appropriate palliative care.

After a patient risk index is calculated and status level assigned, the risk assessment module 115 checks the patient's NFR status. If the patient's status is for resuscitation then the communications process is executed in a standard manner. Where a client is designated NFR, the system runs through another decision process, as described below.

If a patient is designated NFR but requires aggressive medical treatment, the patient shall receive full treatment to aid recovery other than resuscitation in the event of a cardiac arrest. Accordingly, the patient's status level can only ever be within the 0-4 range as resuscitation is no longer an option and the cardiac arrest team will no longer be called in the event of a cardiac arrest. The patient will, however, undergo aggressive treatment to assist in recovery.

A patient who is terminally ill and designated NFR is assessed outside the main risk assessment procedure and only in reference to the following pain score. As resuscitation and aggressive treatment are not viable treatment options, the patient's status level will be modified accordingly to a maximum of status level 3 according to the following table:

Pain/Comfort score	Status Level	
0-2	0	
3-4	1	
5-7	2	
8-10	3	

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The pain/comfort score is determined according to known methods.

The status level and any intervention requirements for that status level will be handled pursuant to normal operation of the communications module 120: The risk index calculation rules described above do not apply to NFR/Palliative care patients. A NFR order can only be assigned or reassigned to a patient by the patient's primary health care provider or the physician's immediate manager.

A nurse or physician may at any time manually upgrade a patients risk status level to any higher level using a "User Activated Alarm" feature 395 on the bedside application

interface (eg. electronic tablet). A user cannot manually downgrade a risk status or an intervention activity request. This feature may be used when it is obvious that a patient is experiencing an emergency situation. For example, the patient may have fallen out of bed and struck her head and is bleeding profusely.

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Referring now to Figure 2, a patient care process 200 is described. The process 200 is initiated following admission of the patient to the hospital at 205. Following admission, a patient record is established at 210 by a nurse or administration staff, for example. If the patient has not previously been a client at the hospital, a patient profile having all pertinent personal and physical data is established. If the patient is an existing client at the hospital, the nurse need only establish a new record for that patient to correspond with the patient's current health complaint. In order to establish the patient record and/or profile at 210, the nurse may query or interface with the administration system 105 at 215.

Once a patient record is established for the patient at 210, the patient undergoes clinical 15 observations and data is collected concerning the patient's health and physical state at 220. This data is captured through capture devices 135, transmitted over a LAN to data repository 110 and processed by risk assessment module 115 so as to calculate a patient risk index at 225. If the patient's risk level is considered to be within an acceptable range (ie. less than level 1) at 230, the patient continues to undergo clinical observation at 220. 20 Otherwise, if the risk level indicates that the patient should be attended by health care personnel, a status level is assigned at 235. This step of assigning a status level may directly correspond to the calculated risk or may additionally take into account personal or general patient characteristics such as age, weight, sex or past medical history. Once a risk 25 status level is assigned to the patient at 235, the corresponding intervention activity is determined at 240 according to the hospital's desired procedures. An intervention resource is then assigned at 245, depending on the determined intervention activity and the available human resources (checked against the human resource's availability module 125 at step 250).

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Once an appropriate health care provider is identified and assigned at 245, one or more

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communications devices associated with the health care provider, for example such as a mobile phone, pager or personal digital assistant is identified at 255 and contacted at 260, requesting attendance on the patient. Step 260 involves transmission of a suitable message to the assigned communication devices, requesting attendance, identifying the risk level and requesting an affirmative response. At 265, if the health care provider responds (in one more of the methods described later in relation to Figure 9), and the health care provider attends the patient at 270, treatment is administered at 275. If the health care provider does not respond at 265 to the request for intervention, an alternative communications device may be assigned at 255 and contacted at 260 or an alternative health care provider may be assigned at 245, depending on the risk level of the patient. This is also the case if a health care provider responds at 265 but does not attend the patient at 270.

Once treatment is administered to the patient at 275, the patient's condition is assessed at 280 and, if considered not to be stable, the patient continues to undergo clinical observation at 220. Otherwise, the patient's condition is considered to be stable at 285 and the patient may or may not undergo further clinical observation at 220.

Thus, as will be appreciated from the above description of the patient care process 200, each patient is monitored and is attended by appropriate health care personnel in a cyclical procedure in such a way that ensures that the patient is not overlooked or forgotten by a particular health care provider.

Reference will now be made to Figures 3 to 8 and corresponding functions of the risk assessment module 115. Figure 3 shows an overall risk assessment process 300, beginning with the reception of data from data repository 110 at 305. This received data falls into five categories relating to the five health systems to be observed for each patient. The data is analysed concurrently at steps 310, 315, 320, 325 and 330, corresponding to respective neurological, respiratory, cardiovascular, urinary and temperature systems for each patient. These processes are described further in relation to Figures 4 to 8 below. Each of these processes generates a risk level output. At 335, the outputs of the five health systems are

combined according to the previously described risk index calculation rules and a status level is assigned to the patient at 340. If the patient's risk status level is within the expected range (ie. less than one) at 345, the patient is considered to be stable at 380. At 385, the attendant nurse will determine whether the patient is ready for discharge and, if so, the patient will be processed for discharge at 390. Otherwise, the patient will continue to undergo clinical observation.

If the assigned risk status level is in a range which indicates that the patient's health may be unstable, a check is made at 350 as to whether the patient has a not for resuscitation (NFR) order in place. For most patients, this will not be the case and the process 300 will proceed to initiate communication with appropriate health care personnel via the communications module 120 at step 375. For those patients with an NFR order in place, there is a further check at 355 as to whether aggressive medical treatment is required. If so, a modified risk status level is assigned at 360 according to the procedure described above. If aggressive medical treatment is not required, a palliative care pain score is assigned at 365 and a corresponding risk status level assigned at 370, according to the procedure described above. Once any modification to the risk status level is made at 360 or 370, appropriate health care personnel may be contacted at 375.

A user activated alarm on any one of the capture devices 135 may be actuated at 395 to escalate the risk status of the patient if it is deemed necessary by attendant clinical staff.

Referring now to Figure 4, a neurological analysis process 400 is initiated from step 310. As a first step in process 400, the level of consciousness of the patient is determined at step 405. If the patient has lost consciousness, risk level 5 is assigned at 410. If the patient is conscious, the patient's response to pain stimuli is observed at 415. If the patient only responds to pain stimuli, risk level 4 is assigned at step 420. Otherwise, the patient is observed for confusion, drowsiness, delirium at step 425. If any such observations are present, a risk level of 2 is assigned at step 430. If the patient's level of consciousness is such that he or she is fully aware and conscious and capable of appropriate mental function at 435, a risk level of 0 is assigned at 440. Once the risk level is assigned at 410, 420, 430

or 440, the risk index is determined at 335, either based on the assigned risk level alone or in combination with other patient-related or statistical factors.

Referring now to Figure 5, a respiratory analysis process 500 is illustrated, having been initiated at step 315. At step 505, if the patient's respiratory rate is determined to be nil, a risk level of 5 is assigned at step 510. If the respiratory rate is greater than 40 breaths per minute or less than 6 breaths per minute at 515, a risk level of 3 is assigned at 520. If the respiratory rate is between 30 and 39 breaths per minute at 525, a risk level of 2 is assigned at 530. If the respiratory rate is between 20 and 29 breaths per minute at 535, a risk level of 1 is assigned at 540. If the patient's respiratory rate is between 7 and 19 breaths per minute at 545, a risk level of 0 is assigned at 550.

If a patient's oxygen saturation level is less than 90%, whether that patient is receiving extra oxygen or not, this is considered to be an indicator of greater risk and the risk level assigned at 520, 530, 540 or 550 is increased by 1 at step 560. Otherwise, the process 500 proceeds to calculate and assign the risk status level at 335.

Referring now to Figure 6, a cardiovascular analysis process 600 is illustrated. This process 600 is initiated at step 320 and begins with an examination of the heart rate at 605.

20 If the patient's heart rate is greater than 150 beats per minute, a risk level of 3 is assigned at 610. If the patient's heart rate is between 130 and 150 beats per minute at 615, a risk level of 2 is assigned at 620. If the patient's heart rate is between 100 and 129 beats per minute or less than 50 beats per minute at 625, a risk level of 1 is assigned at 630. If the patient's heart rate is in the normal range of between 50 and 100 beats per minute at 635, a risk level of 0 is assigned at 640...

In addition to examining the patient's heart rate, the patient's blood pressure is examined at 645, if the patient's blood pressure is unrecordably low, a risk level of 5 is assigned at 650. If the patient's systolic blood pressure is less than 60 mm of mercury at 655, a risk level of 4 is assigned at 660. If the patient's systolic blood pressure is between 60 and 80 mm of mercury at 665, a risk level of 3 is assigned at 610. If the patient's systolic blood pressure

is between 80 and 90 or greater than 200 mm of mercury at 670, a risk level of 2 is assigned at 620. If there is a decrease in systolic blood pressure of greater than 30 mm of mercury in two consecutive observations at 675, a risk level of 1 is assigned at 630. If the patient's systolic blood pressure is between 90 and 200 mm of mercury at 680, a risk level of 0 is assigned at 640. Once the heart rate and blood pressure analysis are performed, the risk index is calculated and status level assigned at 335.

Referring now Figure 7, a urinary system analysis process 700 is performed, beginning with step 325. If it is observed at 705 that urine output occurred in the last eight hours, a risk level of 0 is assigned at 715. Otherwise, a risk level of 2 is assigned at 710, following which risk index calculation and status level assignment are performed at 335.

Referring now to Figure 8, the temperature system analysis process 800 is performed, following initiation at step 330. If the patient's temperature is less than 35°C at 805, a risk level of 2 is assigned at 810. If the patient's temperature is greater than 40°C at 815, a risk level of 2 is assigned at 820. Otherwise, if the patient's temperature is between 35 and 40°C, a risk level of 0 is assigned at 825. Once the risk levels are assigned, the risk index calculation and status level assignment are performed at 335.

The data repository module 110 and risk assessment module 115 capture, analyse, assess and determine an intervention level. The communications module 120 delivers the alert message requesting intervention activity and patient information to the responsible physician. There are two key functions of the communications module 120: to alert the relevant health care personnel that the patient requires attention; and to escalate the alert where appropriate.

Referring now to Figure 9, the function of the communications module 120 is described. A communications procedure 900 is initiated following receipt of input from the risk assessment module 115 at step 905. If the determined risk level is level 5 at 910, a cardiac arrest team is notified at 920. In the sense employed in this specification, the term cardiac arrest should be understood to indicate a serious health risk, rather than only indicating a

situation where the patient's heart has stopped. Accordingly, the term cardiac arrest is used herein in a broad sense to indicate a serious health condition requiring immediate intervention, such as when the patient has lost consciousness or has stopped breathing. If at 912 a risk level of 4 was assigned to the patient, a medical emergency team 922 is assigned to the patient. If at 914 a risk level of 1 to 3 was assigned, a primary health care provider is assigned to the patient at 924. If at 916 a risk level of 0 was assigned to the patient, it is considered that no further action is required at 926. If a health care resource is required to attend the patient, such a resource is assigned at 930.

Status level 3-5 intervention activities may require differing levels of medical seniority and specialisation. For example, status level 5 requires cardiac arrest team at 920 intervention while status level 3 may only require a junior doctor or ward nurse at 924. The administration system 105 enables hospital administrators to assign different levels of health care personnel to requests for interventions.

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Status level	Required Intervention Activity	Response Resource Required
0	Patient data is within expected range and patient's overall condition is described as stable	• NIL
	Non Urgent Review (3-8 hrs); Patient observations are moderately outside the expected range	 Alert / Information sent to patient primary health care provider Nurse/junior physician
2	Timely review required (1-3 hrs); patient observations are materially outside expected range	Registrar level response
3	Urgent Assessment required (10-60 minutes)	Registrar level response

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4	Immediate response required (0-10 minutes)	Registrar/Consultant Medical Emergency T
		Team Outreach
5	Cardiac arrest (immediate)	Cardiac arrest team

The hospital can configure its individual risk profile and the type of resource that is required to respond to the various levels outlined above. For example, one hospital may choose to assign nurses to investigate status level 2 patients whereas other hospitals may assign junior doctors.

Having defined a certain status level and type of required response resource, the system 100 can be configured to prioritise the actual human resources that are required to respond. For example, in the case of a status level 3 patient, the patient's primary health care provider may be required to attend at 924. In the event that the health care provider does not respond positively at 945, the communications module 115 then determines the next most appropriate health care resource available at 930 and 935 and contacts that person. Health care providers can be defined by a number of categories including peer group (speciality and sub-speciality), seniority, commercial grouping (eg private practice partners), current rostered resources or any other criteria. The human resource availability module 125 is checked at 937 to ensure that only resources that are listed as available are nominated as intervention resources. The intervention request may be sent at 940 via any one or more of the methods described below:

- 1. The system automatically generates a Short Message Service (SMS) message and sends it to the required health care personnel (HCP) seeking an intervention. It may contain information such as a case number, key identifying details (patient name and ward) and extract of the patient's most recent observation data. Such information is in addition to the risk level and request to respond.
- Message to a pager. The system automatically generates a pager message that is
 sent to the appropriate HCP. In addition to the risk level and request to respond, the
 message preferably contains a case number, key identifying details and an extract

- of the patient's most recent observation data.
- 3. Message to a Handheld Wireless device or PDA. Where the HCP is within the confines of the hospital, the hospital has a wireless network and the HCP has a PDA, an alert will be displayed on the device. The content of the message is the same as for the pager or SMS messages. The HCP may be able to review the patient's data on line from various terminals connected to the administration system 105 and located around the hospital.
- Automatic placement of a telephone call to the HCP's mobile or cell phone. The communication module may automatically generate a voice message or may provide an interactive voice response interface with the HCP in order to convey the relevant patient details.

A health care provider receiving an intervention request has two alternatives:

- 1. He or she can positively accept the intervention request alert by responding at 945
 via a cell or mobile phone (SMS), Interactive Voice Response system (IVR) or
 PDA if they are within range of the hospital's network. The system will then tag
 the health care provider as having accepted the request and he/she will be required
 to attend the patient within the defined standard time frames.
- 2. Reject the request (970, 975) either by not responding to the request within the specified time or by positively rejecting the request via SMS, cell phone, PDA etc.

The health care personnel can respond at 950 via the following mechanisms to a request for intervention:

- SMS. The health care resource replies to the SMS message with a 'Y' (for yes the request is accepted) or 'N' (the intervention request is declined). The server then updates the case to record the health care provider's acceptance or non-acceptance of the request.
- IVR. Where the health care provider receives the request for intervention via a pager he/she will be required to call a toll free number, enter the case number (contained in the pager message), the HCP's hospital ID number and select either 'accept' (for example, in response to the voice message 'press 1 on your phone to

accept the intervention request') or 'reject' ('press 2 on your telephone to reject the intervention request. ')

3. PDA. A health care provider within range of the hospital's WLAN network can accept or reject an intervention request by sending a message through his/her PDA. Where the health care provider rejects the request he/she can, if he/she chooses to, assign the request to another health professional by selecting the relevant name from a drop down menu.

Depending on the risk status level, a health care provider that does not positively reject or accept an intervention request at 945 may be contacted again at 940 after a predetermined time has elapsed (according to the response cycle limits described below). This continues until either the health care provider positively accepts (950) or rejects (970) the intervention request or the response cycle limits (see below) are exceeded at 975. Where the response cycle limits are exceeded, the patient's risk index is automatically amended to a higher level by the risk assessment module 115, a higher level alert status is assigned to the patient and hospital management may be alerted at 980. A new intervention/communications cycle begins at 905 with a higher alert status and assignment of more senior personnel then commences at 930 to expedite the provision of appropriate care to the patient.

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In the event that the health care provider rejects the intervention request at 970 within the prescribed cycle limits, the system then sends an intervention request to the next most appropriate health care provider (930 to 940). If the cycle limit was not exceeded, the risk index and alert status is not escalated.

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Status Level	Intervention	Number of	Recommended
8	response	Communication	maximum time
	requirements	cycles	between cycles
Status level - 0	n/a	n/a	n/a
Status level - I	3-8 hours	4	45 mins
Status level - 2	1-3 hours	3	30 mins

Status level -3	10-60 mins	3	8 mins
Status level - 4	0-10 mins	2	60 secs
Status level - 5	0-1 mins	1	10 secs

A health care provider that accepts an intervention request will usually be required to attend the patient bedside at 960. The resource will have a defined bedside attendance response time standard to meet. For example, a resource that accepts a status Level 5 intervention request may have to meet a standard of attending the patient's bedside attendance within 2 minutes.

Having accepted an intervention request alert at 950 the health care provider will receive a reminder to attend the patient bedside shortly before the bedside attendance time limit is reached. If the healthcare provider does not meet the required response standard at 955, the communications module 120 treats the non attendance as a positive rejection (975) of the request for intervention. The risk index is upgraded and a higher alert status and intervention activity is then requested and the communications module 120 contacts the next most applicable health care resource at 930 as described above.

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In the case where the primary healthcare provider attends the patient's bedside at 960, he or she will be required to log a unique identifier into the bedside PDA/tablet at 962 to positively confirm bedside attendance. The health care provider can enter his/her own details to log attendance or another attending health care provider, such as a nurse, can do it on his/her behalf. When this occurs, all existing intervention requests for that specific patient are cancelled at 967 and a message is sent 969 to other health care providers who may have been requested to attend the bedside. The health care provider administers treatment at 965 and the process of patient observation and risk assessment continues 985.

If a patient's condition normalises after one or more health care personnel have been requested to attend, the existing intervention request is cancelled and the responding resource notified of the cancellation in the same manner as the initial request.

Nurses within the ward in which an intervention request is activated receive an electronic full copy of the status of the request at 942 (although an interface provided by the administration system 105) as the communications module 120 attempts to confirm that a resource is available and responding.

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The human resource module 125 is a very simple labour management tool. Available doctors for intervention requests may be identified using a simple check box mechanism. The communications module then uses this information to determine which health care providers are on call/ rostered and directs intervention requests to these resources.

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The purpose of the event logging and system analysis module 130 is to provide clinical and business metrics that assist in decision-making, process improvement and clinical governance. This module analyses and evaluates the overall performance of doctors and nurses on an individual and event basis. For example, an adverse event (AE) can be analysed across almost any factors or potential contributory cause to provide forensic data and a deeper understanding of why a patient may have had an AE and the contributing factors attached thereto. Where events have occurred that require reconstruction and detailed information, the event logging and system analysis module 130 may assist to determine what happens. This module may also help identify personnel that require additional training for performance or skill deficiencies. The event logging and system analysis module 130 analyses the following activities, responses and results:

- Collation, analysis and interpretation of patient and medical staff data
- Statistical comparisons and risk profiling to detect aberrant processes, responses and procedures
- 25 Benchmarking and reporting
 - Forensic reconstruction of events, decisions and activities that occurred before, during and after an AE

Module 130 also provides a dashboard of operational metrics that provide a business oriented snapshot across key measures such as average stay per patient, bed utilisation, AE incidence, mortality rates and key human resource ratios.

In one embodiment of the system 100, the administration system 105 includes or interfaces with an artificial intelligence engine (not shown) for assisting performance of the risk assessment module 115 in its decision making functions. For this purpose, the AI engine interfaces with the data repository 110, data storage 140 and risk assessment module 115 so as to more intelligently assign risk levels according to received clinical observation data over a period of time. The output of the AI engine is also provided to the event logging and system analysis module 130 to provider further information to assist the hospital management in its decision making.

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The AI engine may provide guidance to hospital management on what benchmarks and algorithm data values are recommended for use within the specific hospital environment. The Medical Committee of each hospital is then responsible for approving and updating the operating parameters within the software. The administration system 105 is configured to maintain a log of approvals and updates and access is restricted to only senior medical staff.

While an embodiment of the system 100 is shown in Figure 1 and has been described in such a manner as to suggest that the administration system 105 is located on the hospital premises, an alternative embodiment of the invention may be more suitable for a hospital care network involving a common hospital management entity or a group of affiliated hospitals using centralised information technology infrastructure. In such a situation, the invention may be provided according to an application service provider (ASP) model 1000, such as that shown in Figure 10. In the ASP model, the administration system 105 is a centralised system in communication with numerous data capture devices 135 and health care providers 145, even though the administration system 105 may be located quite remotely therefrom.

According to the ASP model 1000 of the invention, the patient data is collected at the bedside and transmitted to the remote administration system 105 for processing according to the procedures described above in relation to Figures 1 to 9. Where necessary, the

communications module 120 of administration system 105 communicates with one or more health care providers 145 corresponding to the patients for which data was captured. For example, one hospital location 1010 may have a large number of data capture devices 135 for its patients and a corresponding group 1020 of health care personnel for providing health care to those patients. Simultaneously, another hospital location 1015 may provide its clinical observation data from its capture devices 135 to the central administration system 105 in order for its patients to receive health care from a separate group 1025 of health care providers at that location.

- In this way, according to the ASP model 1000, groups of hospitals, having in the order of 20 or more wards or locations, may employ a central administration system such as administration system 105 so as to save costs instead of establishing a separate infrastructure for each location. Thus, the present invention is suitable for servicing a large number of hospital locations or
- wards but is also suitable to service a single hospital.

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Accordingly, of the invention may be deployed in a wide number of hospital infrastructure environments, ranging from a stand alone PC environment in an individual ward through to an integrated wireless LAN with electronic bedside tablets delivering alerts through a communications gateway direct to health care professionals via PDAs, palmtop computers or mobile phones.

Advantageously, the system is capable of extracting and receiving data from legacy Patient Administration Systems ('PAS') plus core clinical systems including patient and administrative data – personal, administrative, clinical and other details. In addition, the system may extract at least some of the clinical observation data from bedside monitoring devices and/or other diagnostic devices.

Advantageously, the system provides a high degree of user configurability to meet the needs of a diverse range of hospital, – specialist hospital, teaching hospitals, country hospital down to the ward level – i.e. General, Obstetrics, Paediatrics, etc



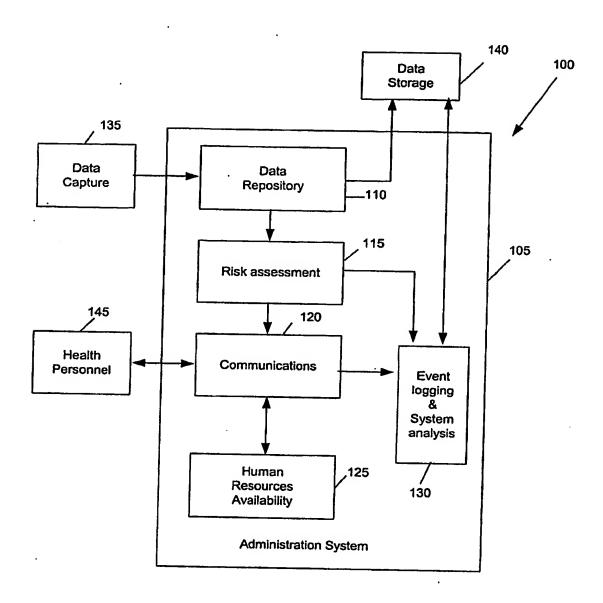


FIGURE 1

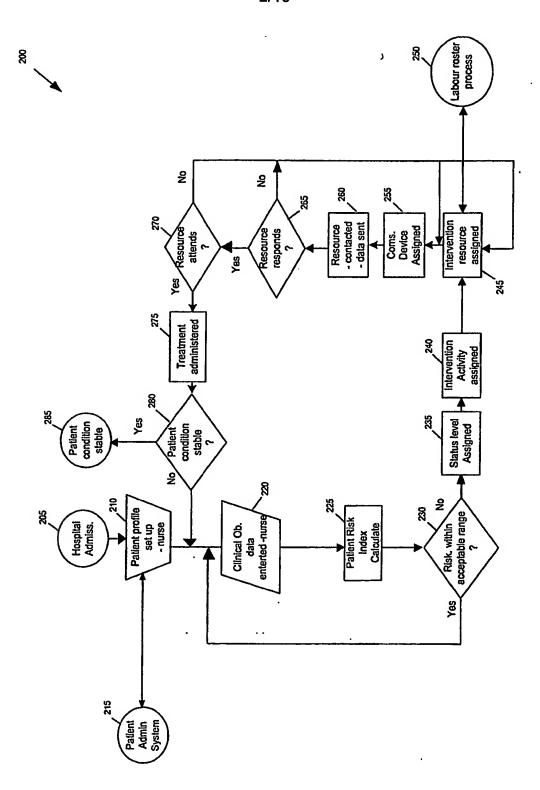
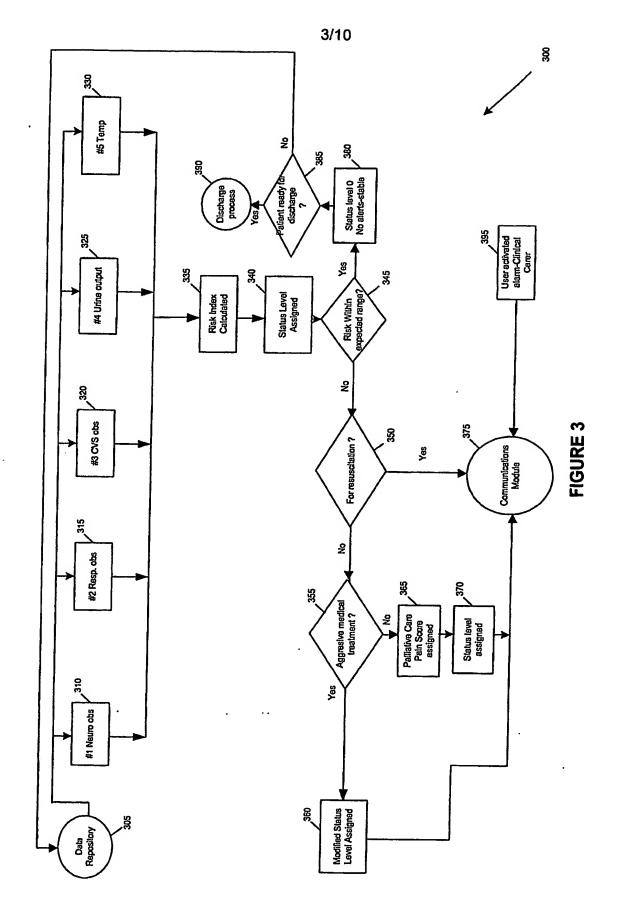


FIGURE 2





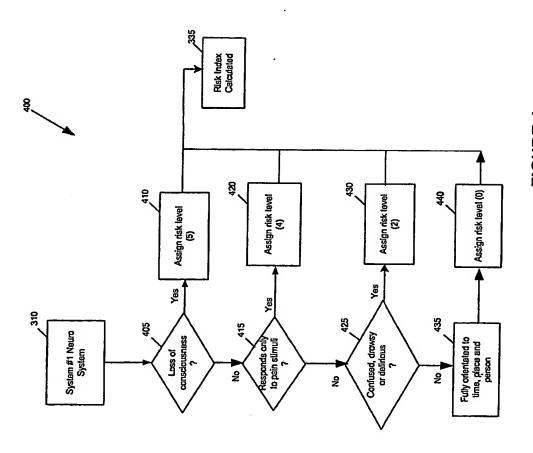
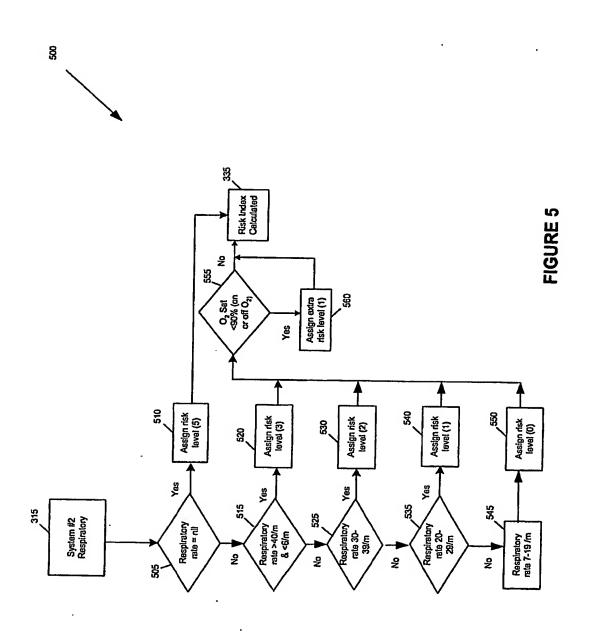
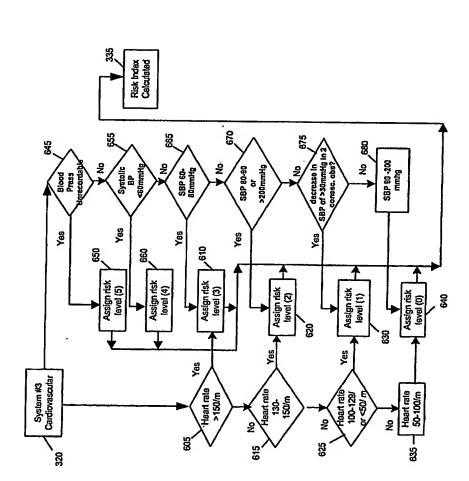


FIGURE 4









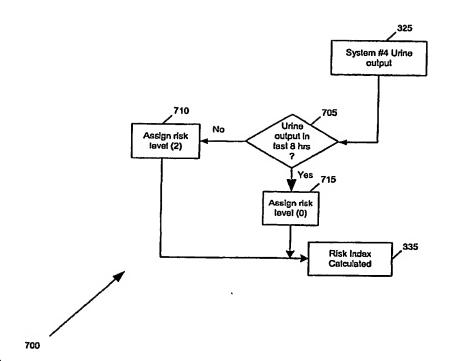


FIGURE 7

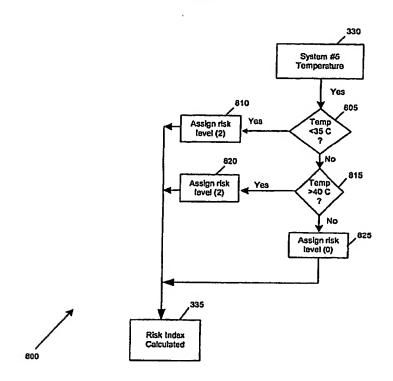
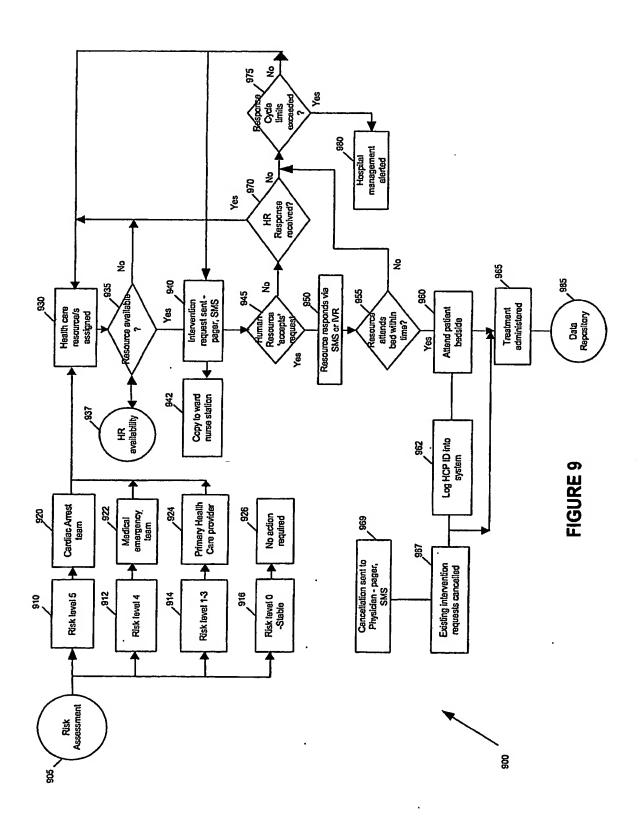
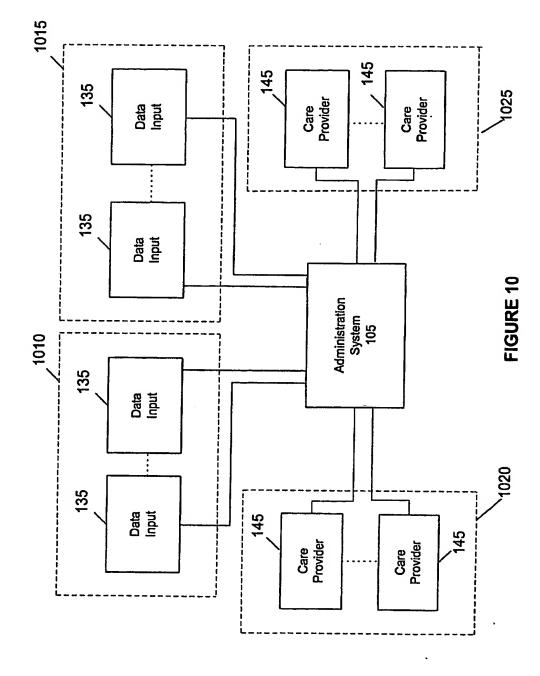


FIGURE 8





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